

REMARKS/ARGUMENTS

The Present Invention

The present invention is directed to a process for providing a human with a therapeutic protein.

The Pending Claims

Claims 15, 20, 25, 26, 30, and 31 are pending.

The Office Action

The Office rejects claims 15-22 and 24-33 under 35 USC 251 and 37 CFR 1.175 as being based upon a defective reissue oath/declaration. The Office Action maintains the rejection of claims 15-20, 24-26, 32, and 33 under 35 USC 251 and 37 CFR 1.658 as allegedly corresponding to the count lost in Interference 104,712. The Office also maintains the objection to claims 15-20, 24-26, 32, and 33 under 37 CFR 1.633 and MPEP 2363.03 on the grounds of estoppel. Further, the Office maintains the rejection of claims 15-18, 21, 22, and 24-33 under 35 USC 112, first paragraph, as allegedly non-enabled. Furthermore, the Office Action objects to claim 25 under 37 CFR 1.75 (c) as being in improper form. Reconsideration of the rejections and objection to the claims is hereby requested.

The Amendments to the Claims

Claims 16-19, 21-24, 27-29, 32, and 33 have been canceled. Claim 15 has been amended to recite that the therapeutic protein is an interleukin and that the autologous human cells are T lymphocytes. Claims 20, 25, and 30 have been amended to reflect the correct claim on which the claim depends. No new matter has been added by way of these amendments.

Discussion of the Rejection under 35 USC 251 and 37 CFR 1.175

The Office rejects claims 15-22 and 24-33 as allegedly based upon a defective reissue oath/declaration. Applicants hereby submit a supplemental oath/declaration (also referring to the instant amendments) which meets the requirements of 37 CFR 1.175. Accordingly, the rejection should be withdrawn.

Discussion of the Rejection under 35 USC 251 and 37 CFR 1.658

Although the Office withdraws the rejection of claims 21-23 and 27-31, the Office maintains the rejection of claims 15-20, 24-26, 32, and 33 as allegedly corresponding to the count lost in Interference 104,712. Specifically, the Office alleges that claims 15-20, 24-26, 32, and 33 do not correspond to claim 7 or 12 of the patent on which the instant application is based, which patent claims were not deemed as part of the lost count of the Interference.

Patent claim 12 is directed to the process for providing a human with a therapeutic protein, wherein the therapeutic protein is an interleukin. Claim 15, before the instant amendment, was directed to a process for providing a human with a therapeutic protein, wherein the therapeutic protein is a cytokine other than TNF. Claim 15, as amended herein, now recites that the therapeutic protein is an interleukin. Therefore, claim 15 is based on patent claim 12, and, therefore, is not directed to subject matter which corresponds to the lost count of the Interference. Further, since all of the instantly pending claims depend on claim 15, all of the claims are based on claim 12, and, therefore, are not directed to subject matter which corresponds to the lost count. Accordingly, the rejection under 35 USC 251 and 37 CFR 1.658 should be withdrawn.

Discussion of the Rejection under 37 CFR 1.633 and MPEP 2363.03

Although the Office withdraws the objection to claims 21-23 and 27-31, the Office maintains the objection to claims 15-20, 24-26, 32, and 33 on the grounds of estoppel. The Office specifically alleges that applicants did not attempt to separate the subject matter of patent claims 7, 10, and 12 from the count.

During Interference No. 104,712, applicants submitted Anderson Preliminary Motion No. 5, which sought to designate claims 2-7 and portions of claims 8-14, to the extent that these claims depend on claims 2-7, of the '346 patent as not corresponding to the count. Claims 2-7 are directed to the process of providing a human with a therapeutic protein, wherein the cells are blood cells, leukocytes, lymphocytes, T lymphocytes, TIL cells, or B lymphocytes. Claim 15, as amended herein, now recites that the autologous human cells are T lymphocytes. Therefore, since applicants moved in the interference to de-designate the process, wherein the cells are T lymphocytes, from the count, applicants should not be estopped from claiming this subject matter.

Further, since all of the other pending claims of the instant application are dependent on claim 15, applicants should not be estopped from claiming any of the pending claims.

Discussion of the Enablement Rejection

Although the Office withdraws the rejection of claims 19 and 20, the Office maintains the rejection of claims 15-18, 21, 22, and 24-33 as allegedly non-enabled.

Applicants disagree with the multiple bases of the enablement rejection set forth in the Office Action. For example, it appears that the Office requires actual data evidencing that the claimed process of providing a therapeutic protein to a human actually works, even though applicants have submitted a declaration by Dr. Steven Rosenberg, a co-inventor and expert in the field, which declaration provides his testimony that the process does, in fact, work (see paragraphs 5 and 6 of the Declaration of Dr. Steven A. Rosenberg submitted on August 16, 2005).

Also, it appears that the Office requires that the specification provide specific guidance on making and using cells other than T cells, e.g., B lymphocytes, despite the fact that Dr. Rosenberg has declared that the protocol described in the specification of the instant application could be used for other cells, such as B lymphocytes (see paragraph 3 of the Declaration of Dr. Steven A. Rosenberg). Although the Office cites many journal articles which demonstrate the problems with gene therapy at the time of filing, the Office does not provide any evidence which specifically demonstrates that the protocol described in the instant specification would not work with B lymphocytes.

Further, it appears that the Office requires that the specification provide sufficient guidance to overcome all of the problems in gene therapy that the Office describes on pages 10-13 of the Office Action. However, Section 112, first paragraph, does not require the specification of the instant application to overcome all of the problems set forth in the Office Action. The specification need only teach one of ordinary skill in the art how to make and use the instantly claimed invention. As discussed previously in the Reply to Office Action submitted on August 16, 2005, the instant specification does, in fact, meet the enablement requirement in this respect, such that the claims are enabled.

However, to further prosecution of the instant application and not in acquiescence of the rejection, claim 15 has been amended to incorporate the features of claim 19. Since the rejection as it pertains to claim 19 has been withdrawn, the rejection of claim 15, as amended

herein, should be withdrawn. Further, since all of the instantly pending claims depend on claim 15, the rejection of all of the instantly pending claims should be withdrawn.

In view of the amendments to the claims, the instantly pending claims are enabled. Therefore, applicants request that the rejection under Section 112, first paragraph, be withdrawn.

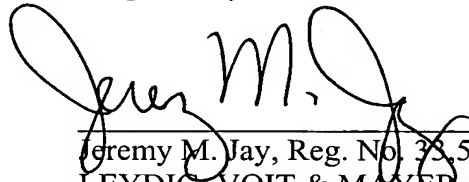
Discussion of the Claim Objection under 37 CFR 1.75 (c)

Claim 25, which is a multiply dependent claim, is objected to, because the claim does not refer to the claims on which it is dependent in the alternative. Claim 25 has been amended to recite "claim 15 or 20." Accordingly, the objection to the claim is moot.

Conclusion

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Jeremy M. Jay, Reg. No. 33,587
LEYDIG, VOIT & MAYER
700 Thirteenth Street, N.W., Suite 300
Washington, DC 20005-3960
(202) 737-6770 (telephone)
(202) 737-6776 (facsimile)

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